

**OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE  
EXECUTIVE OFFICE OF THE PRESIDENT  
WASHINGTON, D.C.  
20508**

---

USTR PRESS RELEASES ARE AVAILABLE ON THE USTR WEBSITE AT [WWW.USTR.GOV](http://WWW.USTR.GOV).

---

**FOR IMMEDIATE RELEASE:  
JUNE 24, 2002**

**CONTACT:**

**2002-56  
RICHARD MILLS  
202-395-3230**

**US Announces Framework to Increase Access to Drugs  
to Fight HIV/AIDS and other Public Health Crises**

WASHINGTON - The United States today announced a framework that would allow poor countries unable to produce pharmaceuticals to gain greater access to drugs needed to combat HIV/AIDS, malaria and other public health crises. This framework would permit a mechanism for easing WTO rules regarding production of these vital medicines. This initiative is part of the Administration's global effort to address the serious health problems, such as HIV/AIDS, afflicting African and other poor developing countries.

These proposals continue the U.S. leadership provided last fall at the World Trade Organization (WTO) Ministerial in Doha, Qatar, where WTO members developed a landmark political declaration on public health and international trade rules (Trade Related Intellectual Property Rights or TRIPS). This declaration affirmed the ability of countries to use the flexibilities in TRIPS to access disease-fighting drugs. It also recognized that some developing countries have insufficient capacity to manufacture pharmaceuticals to address their health crises. WTO Ministers pledged an expeditious solution to this problem and instructed Members to recommend a solution before the end of 2002.

"The Administration has demonstrated its commitment to address HIV/AIDS and other major epidemic diseases," said U.S. Trade Representative Robert B. Zoellick. "Now we are working with other WTO Members on ways to help poorer countries that can't make pharmaceuticals. We believe our proposal offers a way to address major public health crises faced by those most in need."

The U.S. framework, to be formally submitted on Tuesday, June 25<sup>th</sup> in the WTO TRIPS Council in Geneva, sets forth the fundamental aspects of a workable, transparent, sustainable and legally certain solution that will fulfill the Doha Declaration directive.

The U.S. proposal calls for meeting the directive of WTO Ministers in Doha by:

- Ensuring that all poor countries can obtain needed pharmaceuticals for public health crises—even those with insufficient pharmaceutical manufacturing capabilities;

- Ensuring that other developing nations with pharmaceutical production capacity can help supply these poor countries without the risk of running afoul of WTO rules, which should help develop capacity in these developing countries;
- Encouraging Members to establish measures to prevent the diversion of such medicines away from intended recipients in poor countries back to higher-income, developed markets, which would undermine the special flexibilities afforded to poor countries.
- Being part of the growing WTO consensus in favor of using the existing compulsory licensing flexibility under TRIPS Article 31 as the most appropriate solution, rather than by modifying other sections of the TRIPS agreement;
- Continuing examination with other Members to determine the most expeditious mechanism for implementing this solution.

The United States is encouraged by the substantive contributions of other Members toward this common goal and appreciates the communication and cooperation from WTO Members in the development of the U.S. proposal.

## **BACKGROUND**

At the Doha Ministerial, Ministers acknowledged the serious public health problems afflicting Africa and other developing and least developed countries, especially those resulting from HIV/AIDS, malaria, tuberculosis, and other epidemics. Ministers agreed on the need for a balance between the needs of poor countries without the resources to pay for cutting edge pharmaceuticals and the need to ensure that the patent rights system which promotes the continued development and creation of new lifesaving drugs is promoted. One major part of the Doha Declaration was agreement to provide an additional ten-year transition period (until 2016) for least developed countries, as proposed by the United States and agreed upon by all WTO members.

Paragraph 6 of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health recognizes that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement in order to address these health problems. WTO Ministers directed the TRIPS Council to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

We are pleased that several U.S. pharmaceutical companies have formed partnerships with African countries and are working together to address many of the problems related to providing treatment to those in need. This includes the sale of critical medicines at very low prices, as well as the building of an improved infrastructure for getting these medicines to those in need.

Why is this needed? Under current WTO patent rules (Article 31 of the TRIPS Agreement), a country is free to compel a patent owner, under certain conditions, to license another producer to manufacture generic versions of the patented product. This is called compulsory licensing. The Doha Declaration affirmed that Members may use compulsory licensing to address public health crises. A Member issuing a compulsory license may give this license either to a domestic manufacturer or one in another country under certain circumstances. However, under current WTO rules, such licensed production by a manufacturer in another country might nevertheless be infringing if the licensed product is already under patent in that other country. This framework is intended to find a solution to this and certain other problems with the provisions of the TRIPS Agreement.

### **United States leadership**

The United States has been a leader in efforts to harness international trade rules to help countries gain access to life-saving drugs and successfully fight pandemics such as HIV/AIDS.

- In February 2001, the Bush Administration stated the commitment of the United States to a flexible approach that is sensitive to health crises and also protective of intellectual property rights. Under this policy, the Administration has informed WTO Members that as they take steps to address major health crises, such as the HIV/AIDS crisis in sub-Saharan Africa and elsewhere, the United States supports steps by Members to Members avail themselves of the flexibility afforded by the WTO TRIPS Agreement.
- In July 2001, the United States and Brazil agreed to transfer their disagreement over a provision of Brazil's patent law from formal WTO litigation to a newly created bilateral consultative mechanism. The agreement was a positive step in the common fight against HIV/AIDS and the constructive handling of this patent dispute. It permits more effective and less confrontational consideration of intellectual property issues and ensures that such discussions do not divert attention away from the shared goal of combating the spread of HIV/AIDS.
- In Doha in November 2001, the United States provided critical leadership in developing support for a separate, landmark political declaration on public health and international trade rules. This declaration helped pave the way for a successful conclusion of the Ministerial.
- The United States remains the largest bilateral donor of HIV/AIDS assistance, providing 45 percent of all international spending on AIDS. In fiscal year 2003, President George Bush has requested \$1.1 billion to combat HIV/AIDS internationally and has pledged \$500 million to the Global Fund to combat the international scourge of HIV/AIDS, malaria and tuberculosis.

###